

Briefing Paper
Biotech MCAN J-15-27, 28, 29, 30

PART I: BACKGROUND DATA

Program Manager: Jesse Miller

Technical Integrator: Gwen McClung

Review Team: Mark Segal, Ron Ward, Gwen McClung, Ali Muneer,

Options Meeting Date: July 30, 2015

Dispo Meeting Date: July 30, 2015

A. Submitter: DSM Bio-based Products and Services.

B. Chemical Identity:

[REDACTED]

C. Donor Organisms:

[REDACTED]

D. Production volume

i) Maximum PV (Year 3):

[REDACTED]

E. Use:

[REDACTED]

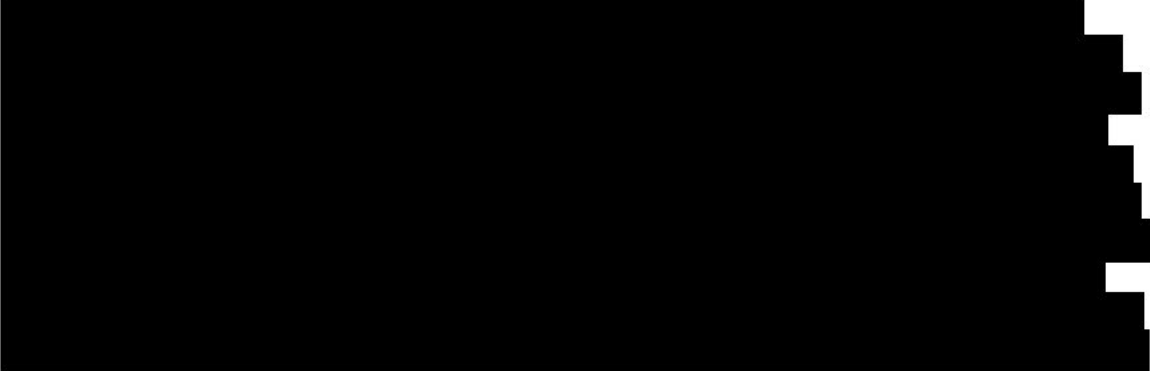
PART II: Recommendation and Rationale

Drop from further review.

[REDACTED]

PART III: Introduction

The Agency has received a Microbial Commercial Activity Notice from DSM Bio-based Products and Services (DSM Nutritional Products) for four intergeneric strains of



PART IV: Risk Summary



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

A. Human Health Hazard

The potential human health hazards associated with the four submission strains have been evaluated by Ward (2015).

[REDACTED]

[REDACTED]

[REDACTED]

B. Ecological Hazards

[REDACTED]

[REDACTED]

Although the production strains may to survive if inadvertently released into the environment, there would be no ecological concerns. *S. cerevisiae* is widespread in the environment, especially in sugar-rich niches (Muneer, 2015).